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An optimized human neural stem cell line (hNSC) for the treatment of traumatic brain injury (TBI)

**Grant Award Details**

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An optimized human neural stem cell line (hNSC) for the treatment of traumatic brain injury (TBI)

**Grant Type:** Therapeutic Translational Research Projects

**Grant Number:** TRAN1-11548

**Investigator:**

**Name:** Brian Cummings

**Institution:** University of California, Irvine

**Type:** PI

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**Disease Focus:** Neurological Disorders, Traumatic Brain Injury

**Human Stem Cell Use:** Embryonic Stem Cell

**Award Value:** \$4,833,271

**Status:** Pre-Active

**Grant Application Details**

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**Application Title:** An optimized human neural stem cell line (hNSC) for the treatment of traumatic brain injury (TBI)

**Public Abstract:****Translational Candidate**

Shef6.1 embryonic cells will be enriched for a neural stem cell marker, CD133. These human neural stem cells (hNSCs) are designated as S6.133.hNSCs.

**Area of Impact**

Shef6.1 human neural stem cells will be tested as a treatment for memory & behavioral deficits resulting from traumatic brain injury (TBI).

**Mechanism of Action**

Traumatic brain injury (TBI) results in loss of neural tissue and chronic inflammation. Additionally, patients may have chronic cognitive and emotional deficits. S6.133.hNSCs have been shown to improve learning and memory, and reduce anxiety in rodent, via replacing lost neurons and glial cells (via cell replacement or neurogenesis), protecting the injured brain from secondary cell loss (trophic effect), and reducing neuroinflammation (via cytokines), possibly by synergic mechanisms of action.

**Unmet Medical Need**

TBI is a silent epidemic, affecting 230,000 Californians yearly (comparable to Alzheimer's), and projected to cost CA \$9.6 billion per year. TBI can lead to significant chronic deficits, yet there are no approved therapies, whether pharmacological or cell based, and few products in the pipeline.

**Project Objective**

We are targeting a Pre-IND meeting by month 30.

**Major Proposed Activities**

- Generate cGMP compatible human neural stem cells (hNSCs) from Shef6.1 embryonic stem cells. Finalize CMC methods and test sterility and stability.
- Test efficacy, safety, dose & immunosuppression in male & female Athymic nude rats, and a non-human primate model (marmoset) of traumatic brain injury
- Finalize target product profile (TPP) and Pre-IND documents with clinical team and consultants at iQVIA; schedule Pre-IND meeting with the FDA.

**Statement of Benefit to California:**

Traumatic Brain Injuries (TBI) are the leading cause of disability. Yearly, 1.7 million American's experience a TBI (~230,000 Californians), costing California ~\$9.6 billion YEARLY. A cell therapy that could reduce inflammation, replace injured brain tissue, or protect host neurons to improve learning and memory could have significant implications for a patient's quality of life and could significantly reduce the economic impact of TBI on the patient, their family, and the state of California.

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